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EXAMINER

BLAKELY III, NELSON CLARENCE

ART UNIT

PAPER NUMBER

1629

MAIL DATE

DELIVERY MODE

09/13/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Application Status

Claims 7-30 and 32-39 of the instant application are pending. Claims 7-28 and 30 are withdrawn pursuant to Applicant's response, filed 06/25/2011. Accordingly, instant claims 29 and 32-39 are presented for examination on their merits.

Applicant's Arguments, filed 06/25/2011, have been fully considered. Rejections/objections not reiterated from previous Office Actions are hereby **withdrawn**. The following rejections/objections are either reiterated or newly applied. They constitute the complete set of rejections/objections presently being applied to the instant application.

Election/Restrictions

As noted on page 2 of the Office action, mailed 03/30/2011, the elected subject matter is drawn to Group II, wherein the elected species, α -ketoglutarate (AKG), appears to be free of the art, and wherein the search has been expanded to include ornithine-AKG, arginine-AKG and glutamine-AKG, according to current Markush practice. However, upon further consideration it appears AKG is not free of the prior art. See *infra*. Accordingly, since the entire scope of the claims was not found to be allowable, claims to all other non-elected subject matter are held withdrawn from further consideration.

Applicant's Amendment

Applicant's Amendment, filed 06/25/2011, wherein claim 29 is amended, claims 7-28 and 30 are withdrawn, and claims 1-6 and 31 are canceled, is acknowledged.

Claim Objections

Claims 34 and 35 are objected to for the following informality:

With regard to instant claims 34 and 35, Applicant is encouraged to indent the claims toward the right so that they are in line with the remaining claims. See instant claims 33 and 36-39.

Appropriate correction is required.

Response to Arguments

The rejection of claims 29 and 32-39 under 35 U.S.C. § 103(a) in the previous Office action, mailed 03/30/2011, is **withdrawn** pursuant to Applicant's amendment, filed 06/25/2011.

Claim Rejections - 35 USC § 103 (New Ground of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29 and 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plouvier *et al.* (US Patent Application Publication No. 2004/0127413A1; cited in a previous Office action), in view of Kristensen *et al.* (J. Anim. Physiol. a. Anim. Nutr., Vol. 86, pages 239-245; 2002; cited by Applicant).

With regard to instant claims 29 and 32-39, Plouvier *et al.* disclose, in reference claims 1-3, 33, 35, 41 and 42, pages 10 and 11, a method of treating a mammal in need of treatment, comprising administering a therapeutically effective amount of the enteric composition comprising at least one compound of the empirical formula (I) to the

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mammal, e.g., human being, suffering from digestive malabsorption and malnourishment, for example. In the instant excerpt, Plouvier *et al.* further disclose wherein the empirical formula (I), i.e., $(X)_{n_1}Y(X)_{n_2}$, comprises wherein n_1 and n_2 are 0, and wherein Y is alpha-ketoglutaric acid (instant claim 29). In paragraphs **[0112]** and **[0116]**, page 5, Plouvier *et al.* disclose wherein the teachings relate to the use of a nutritional material for treating subjects in a malnourished condition, e.g., undernourished patients and anorexic subjects, and the use of enteric compositions for preparing a medicine intended to treat malnourished subjects, or animals. One of ordinary skill in the art, at the time of the invention, would have construed the term "animal" to include the subject matter of instant claims 32-36.

Plouvier *et al.* fail to disclose specifically wherein the amino acid is an essential amino acid, e.g., proline (instant claims 38 and 39). However, Kristensen *et al.* disclose, in the summary, wherein the portal appearance of enteral α -ketoglutarate (AKG) and the effect of enteral or parenteral AKG on portal net appearance of at least proline were investigated in three growing pigs. In the instant excerpt, Kristensen *et al.* further disclose wherein the arterial plasma concentration of AKG increased following both enteral and parenteral administration of AKG, and wherein the arterial plasma concentration of proline increased with the enteral treatment of AKG.

Therefore, a skilled artisan, at the time of the invention, would have envisaged the method of treatment for improving the absorption of amino acids, e.g., proline, in a vertebrate, comprising administering a composition comprising AKG, as disclosed by Plouvier *et al.*, in view of Kristensen *et al.* One of ordinary skill in the art would have

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been motivated to combine the teachings of the aforementioned references when seeking a therapeutically effective medicament, with doses low enough to avoid unwanted side effects, in the treatment of a malnourished vertebrate. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 29 and 32-39, is *prima facie* obvious over the combination of the aforementioned teachings.

Other Matter

It is noted that Application No. 12/626,549 is a divisional of the instant application. However, it is further noted that reference claims 1-6 are substantially similar to instant claims 29 and 32-39.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to NELSON BLAKELY III whose telephone number is (571)270-3290. The Examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey S. Lundgren can be reached on (571) 272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/N. B. III/

Examiner, Art Unit 1629

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1629

September 11, 2011